

## **Texas Woman's University University Regulation and Procedure**

**Regulation and Procedure Name: Human Subject Research**

**Regulation and Procedure  
Number: URP: 02.420**

**Policy Owner: Academic Affairs**

### **POLICY STATEMENT**

All TWU research conducted by any faculty member, staff member, or student using human subjects must have prior approval from a TWU Institutional Review Board (“IRB”) before the research is initiated. The TWU IRBs on each campus (Denton – IRB #00000829, Dallas – IRB #00000844, and Houston – IRB #00000845) review and approve research involving human subjects. The IRBs operate under Federal wide Assurance #FWA 00000178 issued by the U.S. Department of Health and Human Services (“DHHS”). The purpose of this URP is to protect the rights and welfare of research subjects and to ensure that such research is conducted in full compliance with both the letter and the spirit of applicable regulations.

### **APPLICABILITY**

This policy is applicable to TWU Faculty, Staff, and Students.

### **DEFINITIONS**

1. “Research” means a systematic investigation designed to test hypotheses, evaluate programs, draw conclusions, or contribute to generalizable knowledge. Research is usually described in a formal protocol that sets forth objectives and a set of procedures designed to reach those objectives.
2. “Human Subjects in Research” means living individuals about whom investigators (professionals or students) conducting research obtain (1) data through intervention or interaction with individuals, or (2) identifiable private information. Identifiable private information includes any acquired information via self-report, behavior, or observation in which the identity of research subjects is or may readily be ascertained by the investigators or be associated with the information.

### **REGULATION AND PROCEDURE**

## I. Procedures

- A. The purpose of the IRB is to protect the rights and welfare of research subjects and to ensure that such research is conducted in full compliance with both the letter and the spirit of applicable regulations. Failure to obtain IRB approval or to follow approved protocols may result in disciplinary action as described in TWU IRB Procedures.
- B. The IRBs shall apply the following principles in the review of all research involving human subjects:
  - 1. Participation of human beings in research must be voluntary as indicated by free and informed consent.
  - 2. Participants must be protected from physical and emotional discomfort, harm, or danger.
  - 3. Research projects must be designed to benefit participants and/or a larger community whenever possible.
  - 4. The research must be designed to treat all individuals fairly.
  - 5. Commitments made to research subjects must be honored.
- C. The Executive Vice President for Academic Affairs and Provost (“EVPAA/Provost”) is the signatory official who is legally authorized to represent TWU. The EVPAA/Provost appoints IRB members and is responsible for overseeing activities performed by the IRB in accordance with the TWU Federal wide Assurance and Section 45 Part 46 of the Code of Federal Regulations. The Vice Provost for Research and Innovation and Dean of the Graduate School serves as the Human Protections Administrator who is responsible for interface with the DHHS Office for Human Research Protections. The IRB is authorized to revise and update this URP and associated IRB Procedures as needed to reflect new standards, regulations, and University URPs.
- D. Class projects in which data are gathered strictly for educational purposes do not require IRB approval. Such data cannot be reported in any thesis, dissertation, presentation, publication, or other professional venue. If there is a possibility that researchers may use these data for the above purposes, IRB approval is required prior to initiation of the project.

## REVIEW

This policy will remain in effect and published until it is reviewed, updated, or archived. This policy is to be reviewed once every six years. Interim review may be required as a result of updates to federal and state law or regulations, Board of Regents policies, or internal processes or procedures.

## **REFERENCES**

None

## **FORMS AND TOOLS**

None

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| <p><b>Publication Date: 07/02/2021</b></p> <p><b>Revised: 07/02/2021</b></p> |
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